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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,638	12/14/2000	Olivier De La Charriere	016800-429	6191

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/24/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/735,638

Applicant(s)

De Lacharriere

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 18, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26, 28-51, 53, 54, 56-81, 83, 84, 86-111, and 113-120 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26, 28-51, 53, 54, 56-81, 83, 84, 86-111, and 113-120 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

The request for the extension of time and amendment dated 4-18-03 are acknowledged.

Claims included in the prosecution are 26, 28-51, 53-54, 56-81, 83-84, 86-111 and 113-120.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 26, 28-51, 53-54, 56-81, 83-84, 86-111 and 113-120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The newly added independent claims 115-120 recite a method of treating already formed conditions due to already released substance P. The compounds used in the method are substance P antagonists, meaning that these compounds counter-act the effects and not the release of substance P itself. Thus, it is unclear as to what applicant intends to convey by 'eliminate the release of substance P.

Claim Rejections - 35 U.S.C. § 102

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3. **The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 26, 28, 32-34, 45-46, 51, 56-58, 62-64, 75-76, 86-88, 97, 101, 105-106, 111 and 113-120 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/14084.**

WO teaches a method of treatment of skin by the topical application of the claimed P antagonists for the treatment of diseases such as pruritus and urticaria. The compositions are in the form of ointments, creams, lotions and various other forms and contain other additives and therapeutic agents. (note the abstract, page 5, lines 19-20, pages 13-14 and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that WO does not teach the treatment of conditions because of already released substance P. These arguments are not found to be persuasive since the reference teaches the application of the composition containing the same substance P antagonists without an active agent which causes the conditions just as in instant invention. WO teaches P antagonist in a topical formulation such as ointments, creams, lotions and as pointed out before, the very fact that the person has pruritis or skin irritation of the skin indicates the skin of the person was sensitive to the released substance P and the reference

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thus, meets the requirements of instant claims. The mechanism by which the counter-effect of the antagonist occurs has no significance (that is claimed attenuating or eliminating substance P). Besides, applicants themselves have not shown that the antagonists eliminate the release of substance P itself.

Claim Rejections - 35 U.S.C. § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 26, 28, 32-34, 45-46, 51, 56-58, 62-64, 75-76, 86-88, 97, 101, 105-106, 111 and 113-120 are rejected under 35 U.S.C. § 103 as being unpatentable over WO 93/14084.

As pointed out above, this publication teaches a method of treatment of skin by the topical application of the claimed P antagonists for the treatment of diseases such as pruritus and urticaria. The compositions can be in the form of ointments, creams, lotions and various other forms and contain other additives and therapeutic agents. (note the abstract, page 5, lines 19-20, pages 13-14 and claims). WO does not provide any specific examples for the topical application to the sensitive skin. However, based on the teachings of WO it would have been obvious to one of ordinary skill in the art to use the substance P antagonists taught by WO to counter the irritant side effects of a substance in the cosmetic composition due to the release of substance P since the antagonists counter the substance P.

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Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant provides no specific arguments to the 103 rejection. The combined arguments (for 102 and 103) have already been addressed above. With regard to applicant's specific argument that WO does not teach the coadministration of irritants as recited in claims 47-50, 77-80 and 107-110, the examiner points out that these claims recite substances such as proteins, protein hydrolysates and tocopherol as the active agents and not as irritants. It is within the skill of the art to include additional active agents expecting at least an additive effect.

6. Claims 26, 28-51, 53-54, 56-81, 83-84, 86-111 and 113-120 are rejected under 35 U.S.C. § 103 as being unpatentable over Wallengren (contact Dermatitis), Wallengren (BR. J. Dermatitis) in combination with WO 83/01252 and/or WO 93/14084 (all are of record).

Wallengren (Contact dermatitis) teaches that the substance P antagonist Spantide diminishes the contact dermatitis caused by nickel sulfate (note the abstract and page 351).

Similarly, Wallengren (Br. J) teaches the inhibiting effect of substance P antagonists against various irritants (note the entire article).

The WO publications each teach the use of substance P antagonists in medicinal preparations including topical formulations (note the entire publications).

It would thus, be obvious to one of ordinary skill in the art to prepare compositions containing substance P to combat the irritations caused by certain agents, particularly in

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view of the WO publications which show the use of these substances in the medicinal preparations.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicants' arguments are similar to those advanced for the 102 rejection and therefore, the same response is applicable. In summary, the examiner points out that the references clearly teach that the substance antagonists act against the substance P released which causes the irritation and this antagonist effect will be the same whether the substance P is released in a sensitive skin or non-sensitive skin. The rejection is maintained.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility

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that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

June 23, 2003